DRAFT: Interpretation of OFPA and the National List- Analysis Materials
Provisions of the Act
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Justification:
7 USC 6517 of OFPA outlines the procedures that shall be followed for the development and implementation of the National List. It provides the guidelines for inclusion of substances on the list, procedures and criteria that must be followed and outlines the authority of the Secretary and the NOSB. The NOP has requested the NOSB Materials Committee to review the petitioned substances within the context of 7 USC 6517. The specific issue that needs to be addressed is that under Sec. 2118 National List (c) Guidelines for Prohibitions or Exemptions places limits on the types of substances that can be included on the list.

Historical background:

The National List of approved synthetic substances is a compilation of substances that would otherwise be prohibited in organic production. The OFPA (7USC 6517 (c) (1) (B)) states the substance

(i) is used in production and contains an active synthetic ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oil, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines, and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers and equipment cleaners;

(ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern; and

(iii) is used in handling and is non-synthetic but is not organically produced.

The production categories that are defined for active synthetic ingredients were intentionally included in OFPA to limit the scope of the National List and the use of synthetic substances in organic production systems. Many of the material decisions and procedures were established by the early members of the NOSB through consultation with the NOP, the organic industry, private and State certification organizations and through public input. The first proposed National List decisions were made primarily during the NOSB meetings between 1994 and 1996.

The NOP is currently interpreting the National List and its existing annotations when certifiers need clarification on materials described in a farm plan and when petitioners submit substances for review for inclusion on the National List. In 2004, the NOP made two materials interpretations (Phosphoric acid to stabilize aquatic plant extracts and Potassium Lactate and Sodium Lactate for meat processing) for which the NOSB requested a formal clarification in an effort to understand the manner in which the NOP interprets the National List. Members of the NOSB have argued that the combination of generic substances on the list resulting in a synthetic reaction requires an

additional review of the new substance **(i.e. sodium lactate, potassium lactate).** Such a substance is prohibited unless it is reviewed by NOSB, and recommended to be added to the National List. To suggest otherwise removes a key decision from the authority of NOSB as described by OFPA: that all synthetic substances used in production and handling must appear on the National List, which has been recommended by NOSB.

Based on conversations with the NOP staff, their current position is that once an "active" substance is listed (active meaning that a synthetic substance falling in one of the production categories in 6517(c)(1)(B)(i)) then all additives to the active are allowed unless restricted in the annotation that may accompany a substance. This is inconsistent with both the philosophy of what annotations were used for when they accompanied a substance on the List and with the historical view of what needed to be petitioned to the List[1,2] . The annotations that accompanied many of the substances on the List were utilized to narrow the use of the substance within the organic systems (i.e. hydrated lime, lignin sulfonate, lidocaine). For substances extracted from plants, animals or mineral sources they were added to distinguish the synthetic forms from the non-synthetic forms [3]. They were not used to place restrictions on formulations of the substance when used in a brand name product or other commercial formulations (trademarks). In the

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[1] **Orlando 4/95 (starting line 980):** Prior to returning to the discussion of materials, Baker reported to the Board that the impromptu task force had agreed on the following principles:

1. Non-synthetic and allowed synthetic materials may not be combined in formulations with prohibited materials.
2. Carriers, diluents, fillers, emulsifiers, preservatives, excipients, stabilizers, surfactants, wetting agents and other ingredients of formulated products must be consistent with the inerts policy.
3. The use of all materials approved for production must be consistent with their corresponding annotations under the NOP Farm Plan guidelines and with the individual Farm Plan.
4. Procedures to address brand name products will be established at a later time.

The Board agreed in principle without taking a vote.

[2] **Santa Fe (6/94 starting line 425)** states, "A paper prepared by Zea relating to the natural/synthetic dichotomy discussed was taken up next by the Board. Theuer explained his ideas regarding a progressive approach (from synthetic to natural to organic) for substances used for extraction. After agreeing with Zea that solvents would be included on the National List, Friedman moved and Stoneback seconded that "Synthetic substances may be used to extract a substance from a natural source provided that: 1) the chemical structure of the final extracted substance is not changed by the extraction; 2) none of the synthetic substances used to extract remain in the final extracted product; and 3) the substance used to extract the product is approved on the National List ". VOTE: Yes-11, Opposed -0, Absent-2. Motion Passed.

[3] **Orlando 4/95 (starting at line 787)**: Hydrolyzed Aquatic Plant Extracts- Reviewed by Donald Blackeney, Bruce Spencer and James Johnson. Determined to be non-synthetic; Vote: 13 aye/0 opposed, 1 abstention. By the nature of the National List no further action was necessary on this material. An informative discussion ensued before the vote on hydrolyzed aquatic plant extracts. Baker noted that stability is a problem in some solutions, especially plant and fish extracts, and that otherwise non-synthetic formations contain preservatives and/or stabilizers to allow marketability. Sligh and Merrigan stated that the NOSB should just vote on active ingredients at this time and postpone review of inerts and confidential information. Sonnabend introduced the question of whether the solvent used in extraction should affect the determination of whether the active ingredient is classified as synthetic or non-synthetic, noting that the solvents used for plant extraction may be water potassium hydroxide. Sonnabend also asked whether inerts and stabilizers should affect the synthetic/non-synthetic status. Baker noted that the NOSB has not yet decided that extraction with a substance such as potassium hydroxide or ammonia hydroxide makes the end substance synthetic.

Austin 9/95 (starting line 605): Aquatic Plant Extracts (other than hydrolyzed) **(NOSB defined hydrolysis in relation to this substance as a reaction of a substance with water in "NOSB Final Recommendation Addendum 25 Definitions and Interpretations, Austin, 1995"**)- Reviewed by Donald Blakeney, Bruce Spencer. Determined to be synthetic; Vote 11 aye/2 absent. The NOSB's decision to allow this material for use in organic production; Vote 10 aye/1 abstension/2 absent. Annotation: Extraction Process is limited to the use of potassium hydroxide; solvent amount used is limited to that amount necessary for extraction.

preambles to the second proposed rule and the final rule [4],[5] [6]the NOP concurred with members within the organic industry [7]in their recognition that the National list would include all ingredients in agricultural inputs and formulated products and detailed how the primary role of the NOSB would be the review of substances and the development of the National List.

Potential Solution to Resolve Issue:

One category specified in OFPA 6517(c)(B)(i) stipulates that the substance "is used in production and contains an active synthetic ingredient as a **production aid including netting, tree wraps and seals, insect traps, sticky barriers, row covers**

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[4] **The Preamble to the second proposed rule, March 13 2000 Page 80612** states, "synthetic ingredients in any formulated products used as organic production inputs, including pesticides, fertilizers, animal drugs, and feeds, must be included on the National List. As sanctioned by OFPA, synthetic substances can be used in organic production and handling as long as they appear on the National List. The organic industry should clearly understand that NOSB evaluation of the wide variety of inert ingredients and other nonactive substances will require considerable coordination between the NOP, the NOSB, and industry."

[5] **The preamble to Second Proposed Rule, March 13, 2000 Pages 13589-90:** states, "We recognize that inert ingredients in pesticides and similar substances in other formulated products pose one of the most problematic examples of the use of synthetic materials in organic production. For example, verifying the use of inerts and similar substances such as fillers, carriers, additives, and excipients has been difficult because they are not required to appear on ingredient labels, and formulators typically treat product formulas as confidential information. At times, certifying agents have been unable to determine the exact composition of formulated products proposed for use in organic production. In other instances, organic producers have applied formulated products containing inert ingredients and similar substances that are not specifically allowed. We are challenged with balancing standard practice with the strict statutory requirement that producers and handlers apply only those synthetic substances added to the National List. As sanctioned by OFPA, synthetic substances can be used in organic production as long as they appear on the National List. The development and maintenance of the National List has been and will be designed to allow the use of a minimal number of synthetic substances that are acceptable to the organic industry and meet the OFPA criteria."

[6] **The preamble to the Final Rule, Dec. 21, 2000. page 80612** The allowance for EPA List 4 Inerts only applies to pesticide formulations. Synthetic ingredients in any formulated products used as organic production inputs, including pesticides, fertilizers, animal drugs, and feeds, must be included on the National List. As sanctioned by OFPA, synthetic substances can be used in organic production and handling as long as they appear on the National List. The organic industry should clearly understand that NOSB evaluation of the wide variety of inert ingredients and other nonactive substances will require considerable coordination between the NOP, the NOSB, and industry.

[7] **Organic Materials Review Institutes comments on the proposed and final rule to the NOSB:**
The Organic Materials Review Institute commented about the Rule and specifically in regard to substances which include carriers and fillers in organic fertilizers and microbial productions. In their document they state "In general, OMRI supports the proposed rule's requirement for all synthetics to appear on the National List. For the previous rule, OMRI commented that it opposed the extension of the inert ingredients policy to formulated products other than EPA registered pesticides. OMRI raised concerns based on actual experience with the use of synthetic nutrients to fortify products and the inclusion of sewage sludge and industrial hazardous waste as a filler in fertilizer. However, there is a need for a number of synthetic non-active ingredients used as carriers and adjuvants in non-pesticide formulations, particularly fertilizers and foliar applied microbial products. The final rule needs to take into account food-grade preservatives used to stabilize aquatic plant and fish products, in addition to the synthetic acids and bases included in the proposed National List. Most fermentation media to produce compost and soil inoculants are composed primarily of non-synthetic media or synthetic substances on the National List. However, such media may also contain small amounts of nutrients. Small traces of such substances are likely to be present in the final media of some products currently used by organic farmers. These can be safely assumed to have no significant value as synthetic fertilizers. OMRI standards do not allow the use of synthetic biocides to stabilize microbial products that are not on the National List. Various production aids and adjuvants are used to apply soil microbial inoculants. These generic categories appear as synthetics on the National List and therefore it is appropriate for those products to be stabilized though not fortified, with a limited choice of synthetics. Ideally, these will all appear on the National List. As with inert ingredients in pesticides it will take a period of adjustment for the organic industry. OMRI recommends that the NOSB develop a parallel policy to that for pesticide formulations. OMRI suggests another category to be added to the regulatory text to provide a place of listing these items, when recommended by NOSB".

and equipment cleaners. The NOSB should explore the production aid category as the appropriate section to include substances such as carriers, stabilizers, adjuvants, fillers, extractants, excipients and solvents that do have an active function in the formulations of farm production aids such as fertilizers, soil amendments, compost inoculants, sanitizers, aquatic plant extracts, and fish emulsions. Some of these substances are used in the formulations of brand name products while others may be used after a substance is extracted to put it in a form that is functional for on-farm utilization. The materials committee should work with the NOP to explore this possible solution or determine other ways to resolve this important issue. However, the NOP should recognize that such substances are intentionally used for a specific purpose and therefore are 'active' for the purposes of the regulation.

Make the National List consistent with OFPA:

The following provides a brief analysis of the current National List in relation to the OFPA categories. Sections 205.601 (Synthetic substances allowed for use in organic crop production) and 205.603 (Synthetic substances allowed for use in organic livestock production) are not consistent with the OFPA categories. The categories that are included in these sections are related to use restrictions for the substances. For example, 205.601 (i) disease control, lists the synthetic substances that may be used for disease. To be more consistent with OFPA the category should read Copper and Sulfur compounds and list annotated uses (i.e. for disease control) followed by the substances that contain copper and/or sulfur. This would eliminate most of the categories on the list such as rodenticides, herbicides and compost feed stocks. Appendix 1 provides a revised view of Section 205.601 using an ordering system that utilizes the OFPA categories as the first order in the hierarchy. It also demonstrates in the production aid category how substances such as stabilizers, fillers and adjuvants could be included (see category h, Appendix 1). Most of the substances in Section 205.601 fit within the OFPA categories. There are a few substances that do not appear to fall into the OFPA categories and most of them are used in disease control. The NOSB needs to resolve how to include these substances, or remove them from the List. The livestock section of the rule should also be revised to determine if they substances meet OFPA. The handling section of the List is not limited by categories in OFPA, and the Handling Committee has proposed alterations to better accommodate the OFPA distinction between agricultural and non-agricultural substances.

Provide Decision-making Tools:

The NOSB should consider surveying farmers and certifiers on the resources that they utilize to determine whether or not inputs used on the farm are compliant with the National Organic Standards. There is a notion on the part of the NOP that growers may lose their certification because of the use of materials that are not listed on the product label. The NOP has identified pesticide formulations as a major concern because the inerts are not specifically listed on the label. However, many inputs utilized in a farming operation are not specifically labeled. The operator must obtain information about their inputs by contacting manufacturers directly, working with their certifiers to obtain

information, and utilizing resources such as the OMRI lists and information provided from the US land grant colleges, USDA and Appropriate Technology Transfer for Rural Areas (ATTRA). The NOP had issued directives (the inerts directive specifically) that were an attempt in part to solve the perceived problem of the lack of grower information on materials. The materials committee may want to develop a survey tool to determine their knowledge of materials and determine how and where growers obtain information about the National Organic Standards.

Appendix 1: Viewing Section 205.601 Synthetic substances allowed for use in organic crop production using the OFPA Categories

(a) **OFPA Category Equipment Cleaners**- As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

(1) Alcohols.

(i) Ethanol.

(ii) Isopropanol.

(2) Chlorine materials - Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

((4) Hydrogen peroxide.

(5) Ozone gas--for use as an irrigation system cleaner only.

(6) Peracetic acid--for use in disinfecting equipment, seed, and asexually propagated planting material.

(7) Soap-based algicide/demossers.

(b) OFPA Category Soaps- As herbicides, weed barriers, as applicable.

(1) Herbicides, soap-based - for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.
(2) (7) Soap-based algicide/demossers

(c) OFPA Category Soaps- As animal repellents

(1)Soaps, ammonium - for use as a large animal repellant only, no contact with soil or edible portion of crop.

(2) Soaps, insecticidal.

(d) OFPA Category Pheromones- as insect control

(e) OFPA Category: Copper and sulfur compounds- As insecticides.

(1) Copper Sulfate - for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

(2) Elemental sulfur.

(3) Lime sulfur - including calcium polysulfide.

As rodenticides.

(1) Sulfur dioxide - underground rodent control only (smoke bombs).

As plant disease control.

(1) Coppers, fixed - copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, Provided, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.

(2) Copper sulfate - Substance must be used in a manner that minimizes accumulation of copper in the soil.

(3) Lime sulfur

(4) Elemental sulfur

As an algicide

1) Copper sulfate--for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

(f) OFPA Category: Toxins derived from bacteria, As a method of fire blight control

(1) Streptomycin, fo apples and pears only.

(2) Tetracycline (oxytetracycline calcium complex)

(g) OFPA Category: Horticultural oils: as insecticides

(1) Oils, horticultural - narrow range oils as dormant, suffocating, and summer oils

As plant disease control

(1) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.

(h) OFPA Category: Production aids

As weed barriers

(1) Mulches.

(i) Newspaper or other recycled paper, without glossy or colored inks.

(ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).

As compost feedstocks.

(1)Newspapers or other recycled paper, without glossy or colored inks.

As insecticides

(1)Sticky traps/barriers

(i) Ammonium carbonate - for use as bait in insect traps only, no direct contact with crop or soil.

As floating agents in postharvest handling.

(1) Lignin sulfonate.

(2) Sodium silicate - for tree fruit and fiber processing.

As plant growth regulators.

(1) Ethylene gas - for regulation of pineapple flowering.

****As fillers in fertilizers**

(1) Lignin sulfonate.,chelating agent in fertilizers , dust suppressant

****As stabilizers in aquatic plant extracts**

****As adjuvants in fertilizers**

(i) OFPA Category Fish emulsion. As plant or soil amendments

1) Aquatic plant extracts (other than hydrolyzed) - Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.

(2) Liquid fish products - can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

(j) OFPA Category Vitamins and Minerals: As plant or soil amendments

(1) Elemental sulfur.

(2) Humic acids - naturally occurring deposits, water and alkali extracts only.

(3) Lignin sulfonate - chelating agent, dust suppressant, floatation agent.

(4) Magnesium sulfate - allowed with a documented soil deficiency.

(5) Micronutrients - not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.

(6) Soluble boron products.

(7) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

(8) Vitamins, B1, C, and E.

Other Vitamin and Mineral uses

(1) Boric acid – as structural pest control, no direct contact with organic food or crops.
(2) (2) Hydrated lime as disease control

As Rodenticides

(1) Vitamin D3.

(k) OFPA Category: As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4 - Inerts of Minimal Concern.

(2) EPA List 3 - Inerts of unknown toxicity - for use only in passive pheromone dispensers.

SUBSTANCES IN SECTION 205.601 THAT DO NOT FIT INTO OFPA CATEGORIES

. {Mineral used for disease control]

(3) Hydrogen peroxide..

(4) Peracetic acid - for use to control fire blight bacteria.

(5) Potassium bicarbonate